REMARKS

Applicants thank the Examiner for courtesies extended in the Interview of May 16, 2006, as well as for entering the Amendment and Response that was filed after final on May 11, 2006. In addition, the helpful remarks in the Office Action mailed June 12, 2006 are appreciated, as is the Examiner's careful consideration of this application.

Applicants also thank the Examiner for withdrawing the obviousness rejections based on the cited Verma and Chang references. Applicants agree that there is no motivation to combine the teachings of these references. In particular, the combination of the references does not provide motivation to (1) develop a safer system or (2) to make more space in the vector genome. Neither reference would lead the skilled artisan from one teaching to the other to develop a lentivirus-based retroviral vector system that lacks functional Tat and is capable of producing a replication defective vector for gene delivery and the transduction of target cells.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 63-81 are pending in this application; claims 63, 73, and 78-80 are amended. Support for the amendments can be found throughout the specification. Particular support can be found, for example, on page 4, lines 25-26. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather, the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the amendments should not give rise to any estoppel, as they are not narrowing amendments.

II. THE ART REJECTIONS ARE OVERCOME

Claims 63-65, 68-74 and 77-81 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Luznik *et al.* Claims 63-74 and 77-81 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Luznik *et al.* in view of Bray *et al.* or Hammarskjold *et al.* The rejections are traversed and are addressed collectively.

Luznik *et al.* relate to HIV-based tat-minus proviral clones which were generated by the mutation of wild-type infectious HIV-1 and HIV-2 clones. The Examiner interprets these tat-minus clones to be replication defective vectors when transfected into U937 cells (and when not

rescued by tat-expressing cells or replication inducers such as phorbol esters). To the contrary, these tat-minus proviral clones are not replication defective vectors because they are not capable of virus production (see Fig 1(c), lanes 2 & 4). Therefore, they would not have the capabilities of a replication-defective vector (*i.e.*, gene delivery and transduction of target cells). Moreover, the viruses produced from the proviral clones that infect MT4 cells, which the Examiner refers to in the Office action, are replicating viruses (see Fig 2), and not replication defective vectors as required by the claimed invention.

Therefore, Luznik *et al.* cannot anticipate the claimed invention because they do not teach a replication defective retroviral vector, nor do they teach a vector production system. In addition to being distinguishable on that point, the present invention incorporates another feature that is not taught by Luznik *et al.*: the claims have been amended to recite a "set" of expression constructs or DNA constructs. While this limitation is not necessary for patentability over Luznik *et al.*, it is added to advance prosecution. It is clear from the teachings in the specification that a set is at least two (*i.e.*, two or more) separate constructs. For example, the paragraph beginning on page 4, line 20, describes a construct comprising a packagable RNA vector genome. That paragraph goes on to say that this construct "may be provided as part of a set of DNA constructs also encoding some or all of the structural components of the vector particles." "Set" has also been used in other contexts in the application to indicate more than one (*e.g.* a "set" of nucleic acid sequences).

Therefore, the present claims, in reciting a "set" of constructs, require more than one construct in the vector production system. To the contrary, the proviral tat-minus clones of Luznik *et al.* can only be interpreted as one intact construct, since these clones are generated through the mutation of wild-type clones.

Accordingly, Luznik *et al.* do not anticipate, nor do they teach or suggest the claimed invention. The deficiencies of Luznik *et al.* are not fulfilled by the teachings of either Bray *et al.* or Hammarskjold *et al.* As such, the 103 rejection, similarly based on Luznik *et al.*, is overcome for the reasons stated above.

Reconsideration and withdrawal of the art rejections are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the undersigned if any issues arise that can easily be addressed telephonically.

Respectfully submitted,

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